

FROM :

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PHONE NO. :  
STEINBERG & RASKIN, P.C.

Jul. 21 2000 04:08PM P9  
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**UNITED STATES PATENT AND TRADEMARK OFFICE**

Inventor : Milton Hodosh  
Serial No. : 09/072,504  
Filed : May 4, 1998  
For : **METHOD AND COMPOSITION FOR  
PREVENTING TOOTH  
HYPERSENSATIVITY WHEN USING  
PASSIVE BLEACHING AGENTS**  
Art Unit : 1614

#19  
Eugene  
5-19-01

**AFFIDAVIT OF MILTON HODOSH  
UNDER 37 C.F.R. 1.608(b)**

I, Milton Hodosh, declare as follows:

1. I am the sole inventor named in U.S. Patent Application 09/072,504, filed May 4, 1998.
2. I am a doctor of dentistry with over twenty years experience in the dentistry field and have extensive experience conducting dental bleaching treatments and other dental treatments which may cause hypersensitivity to the patient. In addition I have extensive experience and several patents, relating to the use of desensitizing agents including KNO<sub>3</sub>, to prevent hypersensitivity.

3. With regard to claim 1 of the Fischer I patent (U.S. Patent No. 5,851,512) it would in my opinion have been obvious to one skilled in the art at the time the invention was made to omit the bleaching agent from composition of the proposed count where only a desensitizing effect was desired to thereby obtain the composition recited in claim 1 Fischer I patent.

4. With regard to claim 18 of the Fischer I patent it would in my opinion have been obvious to one skilled in the art at the time the invention was made to neutralize the carboxypolymethylene to obtain a dental composition having a pH range from about 4 to about 9.

5. With regard to claim 20 of the Fischer I patent it would in my opinion have been obvious to one skilled in the art at the time the invention was made to neutralize the carboxypolymethylene to obtain a dental composition having a pH range from about 5 to about 7.

6. With regard to claim 1 of the Fischer II patent (U.S. Patent 5,855,876) it have been obvious to one skilled in the art at the time the invention was made to omit the bleaching agent from the composition of the proposed count where only a desensitizing effect was desired to thereby obtain the composition recited in claim 1 Fischer II patent.

7. With regard to claim 12 of the Fischer II patent it have been obvious to one skilled in the art at the time the invention was made to omit the bleaching agent from the composition of the proposed count where only a desensitizing effect was desired to thereby obtain the composition recited in claim 12 Fischer II patent.

8. With regard to claim 17 of the Fischer II patent it would in my opinion have been obvious to one skilled in the art at the time the invention was made to neutralize the carboxypolymethyene to obtain a dental composition having a pH range from about 4 to about 9.

9. With regard to claim 16 of the Fischer III patent (U.S. Patent 5,985,249) it would in my opinion have been obvious to one skilled in the art at the time the invention was made to treat the dental composition with a base to obtain a dental composition having a pH range from about 5 to about 7.

10. With regard to claim 18 of the Fischer III patent it would in my opinion have been obvious to one skilled in the art at the time the invention was made to treat the dental composition with a base to obtain a dental composition having a pH range from about 5 to about 7.

11. With regard to claim 15 of the Fischer IV Patent (U.S. Patent 6,036,949) it would have in my opinion been obvious to one skilled in the art at the time the invention was made to provide a dental composition having a pH range from about 4 to about 9.

12. With regard to claim 17 of the Fischer IV it would have in my opinion been obvious to one skilled in the art at the time the invention was made to provide a dental composition having a pH range from about 5 to about 7.

13. With regard to claim 17 of the Fischer IV it would have in my opinion been obvious to one skilled in the art to employ an antimicrobial agent as an active ingredient.

14. On a date before May 30, 1997 I conceived of a tooth bleaching and desensitizing composition.

15. On a date before May 30, 1997 I formulated a tooth bleaching and desensitizing composition by combining a bleaching agent and  $\text{KNO}_3$ .

16. The bleaching agent I combined with the  $\text{KNO}_3$  was a commercial available bleaching agent known as "Karisma".

17. On information and belief "Karisma" is manufactured by Confidential-Products Co. located at 385 S. Pierce Ave., Colorado Tech Center, Louisville, CO, 80027-3017. On information and belief "Karisma" contains carbamide peroxide as the active bleaching agent and a sticky matrix material that includes carboxypolymethylene.

FROM :

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STERNBERG & RASKIN, P.C.

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18. On a date prior to May 30, 1997 I conducted a test to determine whether the tooth bleaching and desensitizing composition which I had formulated functioned to achieve its intended purposed. The test is described in my research notes a copy of which are attached hereto as Exhibit 1.

19. In the test the tooth bleaching and desensitizing composition was administered to at least nine patients utilizing a dental tray which was adapted to hold the dental composition adjacent a person's tooth surfaces.

20. In each of the nine patients the dental bleaching composition effectively whitened patient's teeth and no hypersensitivity was reported.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code.

5-3-01

Date

Milton Hodosh  
Milton Hodosh

## Research Notes

Combined 5%, 10%, 15%, saturated  $\text{KNO}_3$  with Karisim (Carbamide Peroxide in a glycerine base.) & C.V.S. Oral Bleaching antiseptics (also 10% Carbamide Peroxide in a glycerine vehicle with citric acid, Propylene Glycol, flavor sodium stannate, & water). Karisim received from Dr. Brahma Sharma of Conf. Dental Products, Inc. [REDACTED]

Object - use in combination with peroxide yielding bleaching agent to prevent hypersensitivity seen with high frequencies when passive bleaching products are used especially in trays. [REDACTED]

Study from [REDACTED]  
- Custom Trays made from impression models using the Omnicover - 5%  $\text{KNO}_3$  added to Karisim in 9 subjects  
10% added to C.V.S. in 6 subjects following the addition of 10 more to Carbamide Peroxide to the C.V.S. product - To see if could obtain more bleaching capability & overcome hypersensitivity produced from 20% Carbamide Peroxide.

In all cases no hypersensitivity resulted - the 15% & 20% [REDACTED] (Potassium nitrate) was unnecessary. [REDACTED] M. L. [REDACTED]  
[REDACTED] witness - [REDACTED]

Sylvia Blazar  
Gail Gibbs  
Randy Gibbs  
Judith Litchman  
Barry Cohen  
Fred Blazar  
Belle David  
Estelle Hodosh  
Jean Gilbane

above pts given Xarisma  $\pm 570 \text{ KNO}_3$   
added. no sensitivity encountered

Patients given CSS oral cleansing Antiseptic

Barry Cohen  
Jean Gilbane  
Barbara Shulkin  
Jackie Hodosh  
Judith Litchman  
Michael Connors  
W. Colmore